UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,257	06/06/2001	Robert Hans Meloen	3516.2US	6928

24247 7590 07/16/2003

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	23

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,257	MELOEN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Claims 1-15 are rejected under 35 U.S.C. 251 because the maintenance fee for U.S. Patent No. 5,885,966 due by four years after the issue fee has not been paid, and therefore the reissue procedures are unavailable for this patent. See MPEP 1415.01.

2. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172*(a). The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b).

The Assent Of Assignee filed June 6, 2001 states that title resides in the name of ID-Lelystad. However, this statement is not supported by the Reel and Frame numbers cited in the Assent, which shows that title still resides with Stichting Instituut voor Dierhouderij en Diergezondheid. This statement also conflicts with the Offer To Surrender filed June 6, 2001, which indicates that ID-Lelystad is now sole owner by assignment (see the first paragraph) and that title remains in the name of Stichting Instituut voor Dierhouderij en Diergezondheid and to ID-Lelystad (see the second paragraph). In view of the conflicting statements and evidence of ownership of the patent, the assignee is not deemed to have established its ownership interest in the patent for which reissue is being requested.

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

3. The executed Offer To Surrender Patent form was received on April 22, 1999. However, the Offer is not acceptable because of its conflicting statements as to the ownership of the patent. See paragraph 2 above.

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

4. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,885,966 , which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

5. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The declaration filed June 6, 2001 incorrectly identifies the application serial number and filing date of the patent for which reissue is being requested. See page 1 of the declaration, last paragraph.

The declaration claims priority under 35 U.S.C. 120 based upon PCT International Application Number PCT/NL96/00223. However, application serial no. 08/981,557, which issued as U.S. Patent No. 5,885,966 for which reissue is being requested, was filed under 35 U.S.C. 371 and not under 35 U.S.C. 120 based upon the PCT application.

Claims 1-15 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

6. The claim for priority inserted at the beginning of column 1 of the specification is objected to because: (1) It does not use appropriate language for a claim for priority under 35 U.S.C. 120. The claim does not set forth the relationship, e.g., continuation, divisional, or continuation-in-part, between the PCT application and the U.S. patent applications. (2) U.S. Patent Application Serial No. 08/477,013 is incorrect, and should instead be 08/476,013 (see, e.g., the reissue declaration filed June 6, 2001). (3) The status of the U.S. patent applications should be updated. Correction is required.

7. Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites a "composition in accordance with claims 1". However, claim 1 is drawn to a peptide, not a composition. It is possible that claim 9 should instead depend upon claim 6. For analogous reasons, claim 11 is also indefinite, and it may be that claim 11 also should depend upon claim 6. There is no antecedent basis in the claims for the phrase "the effective amount" at claim 13, line 2. The claims upon which claim 13 depends do not recite or mention "effective amounts".

8. Claims 3, 9, and 14 are objected to because of the following informalities: At claim 3, line 1, "Peptides" should be changed to "Peptide", consistent with the preamble of claim 1. At claim 9, line 1, "claims" should be changed to "claim". At claim 14, line 1, "effect" should be changed to "affect". Appropriate correction is required.

9. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 1 requires at least two contiguous LHRH decapeptide sequences to be present in the peptide. However, dependent claim 5 does not comprise two such sequences because it replaces the pyroglutamic acid residue which is present at position 1 in LHRH (see, e.g., column 1, lines 19-27) with glutamine.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,284,733. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '733 patent anticipate the instant claims.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

12. Claims 1, 9, 11, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the GB Patent 2,228,262. The GB Patent '262 teaches a dimer of [D-Lys^6]GnRH attached to one another through the sidechains of the D-Lys^6 residues. The conjugates are used as a vaccine, optionally in combination with an adjuvant, to down regulate the action of GnRH in mammalian subjects. See, e.g., the Abstract; page 6, line 9 - page 7, line 11; page 8, lines 22-26; page 10, lines 5-10; and the claims. Because the two [D-Lys^6]GnRH monomers are conjugated to one another through the sidechains of the D-Lys^6 residues, they are deemed to be contiguous to one another. The specification does not define "contiguous" as requiring N-terminus to C-terminus linkage.

13. Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over the GB Patent 2,228,262. Application of the GB Patent '262 is the same as in the above rejection of claims 1, 9, 11, 12, and 14. The GB Patent '262 does not teach its dimer conjugates in combination with an adjuvant which is a water-in-oil emulsion. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine the dimer conjugate of the GB Patent '262 with an oil-in-water emulsion because the GB Patent '262 is not limited to the types of adjuvants which can be used, and because the GB Patent '262 discloses that other conjugates of the general formula can usefully be combined with water-in-oil emulsions (see Example 4, page 18, lines 15-22). The GB Patent '262 does not teach an effective amount of its dimer conjugate, although effective amounts of other conjugates of the general formula are disclosed as 20 μg (see Example 4). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal amounts for the dimer conjugates of the GB Patent '262 because dosage is an art-

recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

14. Claims 1 and 6-15 are rejected under 35 U.S.C. 103(a) as being obvious over Potter et al (U.S. Patent No. 5,723,129) in view of the GB Patent 2,228,262 or the GB Patent 2,196,969. Potter et al teach chimeric proteins comprising a leukotoxin fused to GnRH multimers. The chimeric proteins can optionally be linked to a secondary carrier such as KLH and ovalbumin, and can optionally be combined with adjuvants such as oils. The chimeric proteins are used to vaccinate animals, such as to prevent boar taint, i.e. to immunocastrate pigs. Effective amounts range from 1 μg to 1 mg. See, e.g., the Abstract; column 5, lines 34-57; column 10, line 55 - column 11, line 23; column 14, lines 17-49; column 15, lines 39-45; column 16, lines 48-51; and claims 1 and 5. Potter et al teach the use of GnRH polypeptides which differ in sequence from naturally occurring GnRH but which still retain the ability to elicit formation of antibodies that cross react with naturally occurring GnRH, but do not teach the use of specific GnRH polypeptides in which the residue at position 6 is a D-amino acid. The GB Patent '262 teaches GnRH analogs in which residue 6 is D-lysine. The analogs can be used to raise cross reacting antibodies, but have the advantage of being less susceptible to degradation by proteolytic enzymes present in vivo. See, e.g., the Abstract and page 10, lines 5-10. The GB Patent '969 teaches GnRH analogs in which residue 6 is a D-amino acid. The analogs can be used to raise cross reacting antibodies, but have the advantage of improved stability to degradation in vivo. See, e.g., the Abstract and page 2, lines 11-19. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the chimeric proteins of Potter et al in which the amino acids corresponding to residue 6 of GnRH are D-amino acids such as D-

lysine, because such GnRH analogs are generically encompassed by Potter et al and because the British Patent '262 and the British Patent '969 suggest that such modified chimeric proteins would still be immunogenic but would have the additional advantage of being less susceptible to degradation by proteolytic enzymes present in vivo.

15. Claims 2-5 are novel and unobvious over the prior art of record, which does not teach or suggest peptides having the structures required by these claims.

16. The Sequence Listing filed June 6, 2003 has been approved.

17. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
July 1, 2003

BRUCE KISLIUK, DIRECTOR
TECHNOLOGY CENTER 1600